

Metals Assessment Framework

Development of An Action Plan

SAB Briefing

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Risk Assessment Forum



Background

- ❑ There has been considerable interest in the scientific assessments that the Agency conducts on metals and metal compounds as illustrated by recent events surrounding promulgation of the Toxics Release Inventory (TRI) lead rulemaking and development of the Agency's Waste Minimization Prioritization Tool.
- ❑ As a result of discussions within the Agency, with external stakeholders and with Congress, it became clear that the development of cross-Agency guidance for assessing the hazards and risks of metal and metal compounds should be a priority for EPA.
- ❑ The Deputy Administrator therefore decided to initiate a process to address the issues associated with metals that will provide opportunities for external input, peer review and cross-Agency involvement. The Science Policy Council was identified as the appropriate organization for managing this cross-Agency initiative.

Overall Goal of the Metals Assessment Project

The goal of this cross-Agency guidance will be to articulate a consistent approach for assessing the hazards and risks of metals and metal compounds, based on application of all available data to a uniform and expanded characterization framework. Such an assessment would involve reviewing a broad range of physico-chemical properties that may go beyond those encompassed in the Lead TRI Rule and may suggest more of a case-by-case (i.e., metal by metal) approach to evaluating metals and metal compounds. This guidance on approaches to characterizing metals and metal compounds will benefit many of our programs.

Metals Action Plan Workgroup

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Schedule of Activities to Date

SPC Memorandum	<i>December 2001</i>
Formation of Workgroup	<i>January 2002</i>
Stakeholders Meeting	<i>February 20, 2002</i>
Publication of Action Plan	<i>June 11, 2002</i>
Public Comment Period	<i>June 2002</i>
Finalize Action Plan	<i>Pending SAB Advisory</i>

EPA's Draft Action Plan

- ❑ The MAP is the first product of the cross-Agency effort under the auspices of the Agency's Science Policy Council.
- ❑ The MAP is being submitted to the SAB in an Advisory capacity prior to EPA moving forward to implement the Plan.
- ❑ The Plan envisions the development of 2 related documents: A Framework for Metals Assessment and associated Guidance for Characterizing and Ranking Metals.

Components of the draft Action Plan

- The Plan has 3 components:
 - Identifies the primary elements to be addressed in the Assessment Framework and associated Guidance for Characterizing and Ranking Metals.
 - Proposes a structure for the Framework and Guidance.
 - Sets out a process that will culminate in the production of the Framework and Guidance.

Framework for Metals Assessment

The Framework will be patterned after the Agency's Ecological Risk Assessment Framework (EPA/630/R-92/001; February, 1992). The Framework will lay out key scientific principles and issues that need to be addressed in assessing metals; develop conceptual models for different scenarios and types of environmental decisions; and identify the kinds of scientific information, approaches, methods, and models that are available for differentiating among metals as to their human health and ecological risk

Metals Assessment Framework

(continued)

- ❑ Framework will serve as the basis for developing more detailed assessment procedures for metals as needed for specific Agency activities.
- ❑ Framework to be peer reviewed by SAB in June 2003 and completed by December 2003

Guidance for Ranking and Characterization of Metals

- ❑ It will build upon principles and methods identified in the Framework
- ❑ Focus on how they can be applied in a hazard ranking/ characterization context
- ❑ Guidance will be reviewed by the SAB in Nov 2003.
- ❑ EPA will ask SAB to review whether lead and lead compounds should be classified as *highly bioaccumulative* at the same time as the SAB review of the Guidance

Stakeholder Meeting

February 20, 2002

- ❑ **Meeting convened to gather stakeholder input on the scope of the Metals Assessment Framework.**
- ❑ **Charge questions posed to the participants:**
 - **What organizing principles should the Framework follow?**
 - **What scientific issues should the Framework address?**
 - **What methods and models should be included in the Framework?**
 - **What specific steps should be taken to further involve the public and the scientific community?**

Stakeholders Meeting Recommendations

- ❑ The Framework should provide a basis for identifying and prioritizing risks to the environment that is capable of discriminating among metals, metal alloys, and other metal compounds with respect to hazard and risk.
- ❑ The Framework should be developed using sound science, and be sufficiently flexible to accommodate new methods and models.
- ❑ The Framework should allow for a tiered approach to accommodate differences in purpose and availability of data.

Stakeholders Meeting

Recommendations

- ❑ The Framework should recognize that consideration of “inherent toxicity” alone has limited meaning with respect to metals and metal compounds, because whether an inherently toxic metal will actually induce toxicity depends on the extent of bioavailability.
- ❑ The Framework should focus initially on hazard assessment as a screening mechanism while more detailed assessments for metals and metal compounds, identified in the screening process, might include life cycle and uses of metals as well as release and exposure data.

Public Comments Received on the Draft Action Plan

- ❑ **Five sets of public comments received:**
 - ❑ **Department of Energy**
 - ❑ **Copper and Brass Fabricators Council, Inc.**
 - ❑ **Specialty Steel Industry of North America**
 - ❑ **Ad Hoc Metals Coalition**
 - ❑ **Aluminum Association**

Highlights of Public Comments Received on the Draft Action Plan

- ❑ Commenters were supportive of EPA's effort, e.g. "... represents a significant step toward implementing state-of-the-science hazard and risk assessment techniques for metals."
- ❑ Agency has done a good job of summarizing the available literature and current thinking on the issues.
- ❑ Agency should consider the possibility of different frameworks for ecological and human health assessment.

Highlights of Public Comments Received on the Draft Action Plan

- ❑ Consider narrowing the scope to metals and their inorganic compounds, do not address organo-metalics at this time.
- ❑ Framework should differentiate between elemental metal and its compounds and recognize the unique properties of alloys, more emphasis should be given to physical factors to differentiate among metals and compounds.
- ❑ Commenters strongly supported the need for outreach efforts and a transparent process.
- ❑ At the very least, EPA should hold open the possibility of reconsidering past actions as a result of the SAB's deliberations.

❑ Agency should consider the possibility of

Issues and Challenges

- ❑ To meet goals of Framework as laid out in SPC Memorandum
 - Develop Agency guidance for a consistent approach across programs *by December 2003*
- ❑ To meet expectations of stakeholders
 - Develop a new approach for “hazard screen”
- ❑ Balance the goals of SPC initiative and meet expectations of stakeholders
- ❑ Respond to scientific and programmatic challenges

Major Science Issues

Major Science Issues

- ❑ Chemical Speciation
- ❑ Bioavailability
- ❑ Bioaccumulation
- ❑ Persistence
- ❑ Toxicity

Scientific Challenges

Difficult to develop general guidance based on available science

- ❑ Metals exist in a much wider array of physical and chemical forms (“*speciation*”) than organic chemicals, each with unique properties affecting their
 - *Environmental transformation, transport, and bioavailability*
 - *Bioaccumulation, and toxicity*
- ❑ Generalization across metal compounds is difficult, requiring much more chemical-specific understanding and data

Programmatic Challenges

Difficult to develop a consistent approach for all programs based on available science

- ❑ All programs acknowledge the unique properties of metals that make assessment difficult**
- ❑ Programs have different ways of dealing with the unique features of metals due to:**
 - statutory requirements and assessment goals**
 - availability of exposure and effects data**
 - degrees of conservatism**
 - ways of dealing with uncertainties**

Programmatic Challenges

- ❑ Cross-Agency guidance for a consistent approach to assessing potential hazards and risks of metals and metal compounds
 - Human health and ecological risks
 - Applicable to EPA programs (*e.g., priority setting, information collection, site specific assessments, national assessments, standards setting, etc.*)

Charge Questions for the Science Advisory Board Advisory

- Please comment on the soundness of the proposed organizing principles suggested by the public that are reflected in the draft Action Plan for the “Framework for Metals Assessment and Cross-Agency Guidance for Assessing Metals Related Hazard and Risk.”
- Are the issues identified in the Action Plan (chemical speciation, bioavailability, bioaccumulation, persistence, and toxicity) the major issues of concern for improving EPA's scientific assessments of the hazards and risks of metals?
- Has EPA adequately characterized the issues and do the summaries adequately capture the key scientific uncertainties that will need to be addressed by the Framework and the Guidance?
- Can the SAB suggest priorities within the list of issues based on (a) the potential impact on the assessment of risk or hazard and (b) the state-of-the-science and the feasibility of developing guidance in the near term?

Charge Questions for the Science Advisory Board Advisory

- **Are there specific recommendations for the Framework or for the “Guidance for Characterization and Ranking of Metals” (including methods and models) for addressing these issues that are not captured by EPA's Action Plan?**
- **Please comment on the feasibility of the proposed process for drafting the Framework and the Guidance. Will the timeline allow for the scientific issues to be adequately addressed. Are the measures being taken to involve the scientific community and the public adequate?**
- **Please comment on the outline for the Framework and the description of the Guidance. Is it clear and all inclusive?**
- **Are there any additional actions, beyond those proposed in the Action Plan that could improve EPA's scientific assessments of the hazard and risks of metals?**

Risk Assessment Forum Website

<http://cfpub.epa.gov/ncea/raf/rafpub.cfm?ActType=default>